

The Development Of A Quality Management Mechanism In Disease Management: The US Experience And Its Suggestions

Atsushi Kobayashi

Sompo Japan Research Institute Inc.

Abstract

The mechanism for quality management in disease management is one of the issues to be explored within the context of its development. USA has much experience in the development of disease management. This experience will serve as a useful reference and its analysis will bring us many suggestions. We observe in disease management in the USA the feature of robustness of market with huge variety of players and many kinds of purchasers, such as health plans, employers, and governments, service providers such as disease management organization, as well as accreditation organizations, and consultants. The US market benefits from the accumulated experience and practices over the period of a decade or more. Actions in developing the quality management mechanism include accreditation and initiatives by private organizations. Notably, the Disease Management Association of America (DMAA) has labored hard to establish consensus-based outcomes evaluation. US experience tells us that accreditation is useful, but has limitations and requires necessary experiences, and that while consensus on the evaluation of outcomes in disease management has not yet been firmly established, it could be formed through accumulated practices and an exchange of knowledge in a pragmatic approach. Quality management as knowledge management at a societal level or as part of the infrastructure is required. It is no small matter to purposefully create the mechanism of circulation and exchange of expertise and knowledge, and to integrate them.

Key words: quality control mechanism, disease management, USA

❖ Introduction

The modern concept of disease management, which has been extensively developed in the USA, has universal validity. Many countries have introduced disease management and are now developing their own programs within their unique healthcare systems.

Well-designed disease management programs include the process of outcome evaluation and reassessment, and utilize continuous quality improvement. Quality control is therefore theoretically embedded in disease management. But it is not easy

to make it work in practice. The mechanism of quality management is a key issue, often examined in disease management. The USA has a wealth of experience in the development of modern disease management. This experience serves as a useful reference and its analysis will bring us many suggestions.

❖ Background

Most people can conceive the basic concepts important to the realization of quality control. Among them are third-party accreditation and evaluation of outcomes. The information provided by the independent third-party organization contributes to judgment about quality of disease management programs or services. Proper evaluation of outcomes of the programs can be used to eliminate inappropriate aspects of pro-

Received: October 4, 2007

Accepted: October 12, 2007

Correspondence: A. Kobayashi, Sompo Japan Research Institute Inc., 26-1, Nishi-shinjuku 1 chome, Shinjuku-ku, Tokyo 160-8338, Japan
e-mail: akobayashi@sj-ri.co.jp

grams and help maintain desirable ones.

The disease management community in the USA has abundant experience. They have multiple accreditation systems and many different methods of evaluating programs. However, how to measure outcomes is still not yet well established. Nonetheless, the US experience can contribute valuable suggestions to us. There are many activities and a large body of knowledge available. The evolution of disease management in the USA is a great example to analyze the quality management system in its societal context.

In "Crossing The Quality Chasm" the Committee on Quality Health Care in America, Institute of Medicine, points out important matters to be considered in key areas such as increases in chronic disease, revolution of information technology and patient safety. The committee proposed in its report formulating new rules to redesign and improve care, which would advance better quality care and better outcomes¹⁾. Improving healthcare quality and disease management are often cited together. For instance, in 2003 Liza Greenberg, Vice President, Research and Quality Initiatives, URAC, argued the synergy of the rules suggested by the committee with disease management practices²⁾.

Disease management is one of the matters being discussed in the field of quality assurance in healthcare. For example, some textbooks in the USA take it up as topic in various perspectives such as integrated approach or case study^{3, 4)}. The accumulated knowledge about the framework for analysis in these studies will be applied in this paper.

The Donabedian model of classification has three aspects: structure, process and outcomes. We use this model as a framework for discussing the evaluation of quality of care in disease management. It is also our presupposition that anyone cannot assure or guarantee quality and can only increase the probability that care will be improved⁵⁾. People expect assurance of quality in healthcare, but actually only continuous quality improvement can be achieved.

Numerous attempts have been made to evaluate outcomes in disease management programs and many been published in academic journals. But little attention has given to the institutional development of the mechanism to address quality control in disease management from societal point of view.

This paper is intended to discuss the mechanism for achieving the quality control in disease manage-

ment from institutional perspective. However we do not cover the infrastructure of information technology, which is associated with quality improvement¹⁾. Moreover, we are not concerned here with what quality control should be adapted at the individual program level.

❖ US experience

Tracing the process of development

James B. Couch, the editor of "The Health Care Professional's Guide to Disease Management" retraces the early stage of evolution of the disease management in USA as follows⁶⁾. In 1993 the term "disease management" began to be used in pharmaceutical conferences and then became a buzzword during the 1993 through 1997 time period. Many organizations, in addition to the pharmaceutical companies, have engaged in this movement committing financial, technological, and human resources to disease management. The organizations included managed care organizations, pharmaceutical firms, integrated delivery systems/group practices, specialized centers/organizations for medical services, academic health centers/systems, Blue Cross/Blue Shield organizations, indemnity insurers, professional associations, multi-hospital chains, group purchasing organizations, medical device companies, employers and coalitions, pharmaceutical benefit companies, and independent disease management companies. The penetration of disease management is significant today. America's Health Insurance Plans (AHIP) survey found that by 2002, 99.5% of health plan enrollees were in plans that offer at least one disease management program⁷⁾.

In 1999 Disease Management Association of America (DMAA) was founded. Their news release of March 1, 1999 stated that there was no membership organization dedicated to shaping the industry, setting quality standards and providing a forum in which diverse organizations can convene and learn, and DMAA would fulfill this need. The association began as a forum for sharing ideas about quality and its standards. DMAA has been the one and only organization to represent the multiple stakeholders in the disease management community. Their mission is to promote population health improvement through disease and care management by standardizing definitions and outcome measures, and to promote high quality stan-

dards for disease management and care coordination programs as well as support services and related products, materials and services.

Today their definition of disease management is universally cited in documents from various sources, and is accepted as the standard. It has also taken the initiative in standardizing outcome measures. In 2003 the Quality and Research Committee of DMAA announced projects including a white paper on evaluation method, literature database, and consolidation of disease management outcome data from DMAA members and others. In 2004 it published "Disease Management Program Evaluation Guide, First Edition" including principles for assessing disease management to close the gap in the scientific measurement of program in the practices. The guide says that when possible, randomized controlled designs should be applied; however this may not always be possible, and that when use of such design is not possible, quasi-experimental approach such as comparison to an equivalent control group is recommended⁸). The goal was to provide generally accepted and authoritative information on evaluation of disease management outcomes through research activities to review principles, methods and study design, and endeavor to achieving consensus. DMAA has facilitated consensus-building efforts among all those concerned. It organized a roundtable discussion on consensus guidelines for measuring disease management outcomes across various stakeholders such as the U.S. Federal Agency for Healthcare Research and Quality, accreditation organizations, and purchasing groups, in addition to disease management service organizations. The "Outcome Guidelines Report, First Edition" was released in December 2006. In 2007 "Outcome Guidelines Reports Volume II" was released in September following feedback from various parties. DMAA declares its project on consensus-based outcomes evaluation will be continued.

Accreditation has enjoyed wealth of experience in the healthcare history in USA. There have been multiple accreditation organizations and a great variety of accreditation programs. The National Committee for Quality Assurance (NCQA) is among the accreditation organizations which accredits mainly health plans, and administers the Healthcare Effectiveness Data and Information Set (HEDIS) which is designed to provide purchasers and consumers with the information they need to reliably compare the performance

of health care plans. NCQA expects it will contribute to improving health care quality. URAC is another one of the accreditation organizations. Their first accreditation program was designed for health care organizations performing utilization review for medical service providers. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredited mainly medical service providers and gradually has expanded their accreditation coverage. During 2001–2002 year time these organizations introduced their accreditation programs on disease management after the preparation period drawing on their respective expertise and experience.

Health care service is purchased by the private sector, such as employers, and the public sector, such as Medicare or Medicaid, in the USA. The large employers have strong influence. Payer coalitions, which are also called purchasing groups, corresponding to various sizes of businesses and payers have grown to be influential stakeholders and occupy important positions in the quality equation. The purchasing community has paid attention to the quality and cost of disease management. Some purchasing groups provide analysis and advice on the quality and effectiveness of the disease management programs for their members. For example, the Pacific Business Group on Health (PBGH), a California-based business coalition launched the Disease Management Effectiveness Program to evaluate existing disease management programs against criteria endorsed by the experts. They conducted a detailed audit of three types of DM programs for seven California health plans (Aetna, Blue Cross, Blue Shield, Health Net, Kaiser North, Kaiser South and PacifiCare) in early 2002, and released the final report⁹) in November 2002.

Disease management programs in the USA are implemented in two ways: to make/build or to buy. For example, Kaiser Permanente makes or builds their programs by themselves. Whereas, most other health plans implement their disease management programs by buying the services directly from the disease management companies, as do some employers. However, most employers purchase healthcare services from health plans or health insurers that arrange their disease management programs through outsourcing services provided by disease management companies.

It is common that most large-size employers retain consultants specializing in employee benefits

for designing and purchasing healthcare services. Small-size employers can gain similar services through participating in purchasing groups. In the healthcare market, especially employer-based health insurance market, employee benefit brokers play a significant role. They are, however, not necessarily experts in disease management. Expertise in the disease management field is desirable. The Disease Management Purchasing Consortium (DMPC) fills this need. They describe themselves as the largest source of contracting assistance in disease and population management. Their membership consisted of 86 health plans plus 18 private and public sector employers/retirement systems, 2 unions, and 12 state Medicaid programs, covering 80,000,000 lives in total¹⁰.

The government sectors are also significant purchasers of disease management services. Thirty-two states employed disease management programs in Medicaid in July 2005¹¹. At the federal level, disease management has been introduced as a pilot project. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173), the federal agency Centers for Medicare & Medicaid Services (CMS) selected nine chronic care improvement programs after a competitive solicitation. Eight of these programs were launched between August 1, 2005, and January 16, 2006. CMS has submitted the preliminary and first report¹² to the US Congress that illustrated the findings related to quality improvement and health outcomes.

Features of the disease management community

We trace, as described above, a brief overview of the evolution of disease management and its activities in quality control, and have observed some features of the disease management community in USA as follows:

- A. Choice of “make/build or buy” to implement the disease management programs. Market contracting predominates. Purchasers’ views have influence.
- B. Market robustness with a very wide variety of players including many kinds of purchasers such as health plans, employers, and governments, service providers such as disease management organizations, accreditation organizations, and consultants.
- C. Accumulation of experience and practices during the period of a decade or so. Many kinds of trials of disease management programs with a high member penetration and large numbers of participants.

Discussion

Roles in quality assurance

We referred above to accreditation organizations, consultants, and private associations. We will now discuss their roles in the quality management mechanism to promote quality assurance in disease management.

○The concept of disease management and mechanism of quality management:

DMAA considers it the fundamental element of the disease management to evaluate clinical, humanistic, and economic outcomes on an on-going basis with the goal of improving overall health. The attention to quality and cycle of quality control are embedded in the concept of disease management. However, how does this work in the real world?

Persistent struggles for standardizing outcome measures by DMAA tells us it is arduous work. This task involves covering the various and innumerable programs in different situations and conquering the incompatibility between rigorous scientific measurement, such as randomized control trials, and demonstrative measurement in the real business world. “Outcome Guidelines Report, First Edition” by DMAA provides an explanation as follows: Randomized studies don’t exist enough to apply the programs as a whole, and “many “natural experiments” of disease management programs conducted for business rather than research purposes have demonstrated that these programs appear to have value when evaluated as carefully and methodically as their non-randomized control trial setting will permit”¹³.

There is more to the quality management mechanism. The mechanism such as initiatives to advance the momentum in societal context is necessary to realize the concept embedded in programs.

○Accreditation and asymmetry of information / transaction cost:

Accreditation contributes to quality assurance in disease management. The information on the disease management program or organization provided by accreditation organizations can mitigate the asymme-

try of information on the quality for purchasers and enrollees in the programs. Judging the quality of a program during the purchasing process is difficult. From the perspective of transaction cost theory, accreditation assists the purchasers of the disease management services with uncertainty in entering into a contract. The issue of transaction cost could be discussed separately *ex ante* and *ex post* process¹⁴). *Ex post* process accreditations after some period could serve as an alternative. It provides the transparency and accountability in disease management services and promotes continuous quality improvement in the organization. However Donabedian pointed out that external pressures were insufficient to truly motivate individuals and organizations unless they are correspondingly predisposed¹⁵).

Accreditation organizations disclose their methodologies that have been built on their experiences and expertise during their long accreditation history. Their methodologies, however, cover the system or process, and not outcomes. The hardship in the outcome evaluation projects by DMAA suggests the difficulty of establishing common methodology in outcomes measurement in disease management. In December 2006 DMAA and NCQA announced a collaborative agreement to develop performance measures in clinical areas for disease management. Their expertise in measurement will help to further the outcome evaluation project.

○Consultant advising purchaser/asymmetry of information and transaction cost:

An expert consultant advising the purchaser mitigates asymmetry of information between service provider and purchaser before the conclusion of the contract. It also help customer to save the cost of searching for the proper provider.

DMPC is one of the cognoscenti to identify the necessary quality for individual DM program purchasers. It is a sort of consultant and provider of individual solutions for each purchaser. The purchasers ask the disease management service organizations to submit their request-for-proposal (RFP) which defines the requirements of contract. DMPC has drafted many RFPs and developed the methodology of evaluation of outcomes for practitioners. NCQA says that their accreditation is designed to meet many requirements. It has influenced to a great degree evaluation of the quality of disease management.

○Initiative involving and integrating knowledge

diffused in various places:

We understand that the initiative by DMAA in the institutional evolution of quality management in disease management plays the role of involving and integrating knowledge diffused in various places. The process of the initiative has been broad-based and consensus-driven. The knowledge and expertise about quality in disease management spreads through the process. A wide variety of stakeholders including academics, governments, purchasers, service providers and other industry representatives, have participated.

○Pragmatic approach:

It is through shared awareness that disease management continues to develop and innovation will continue. It is impossible to establish static standards and methods by a prescriptive normative approach. A step-by-step approach integrating knowledge is reality-based. Much still needs to be done to achieve a consensus level of evidence in evaluation methodology.

Institutional complementarities

We should also pay attention to the issue of institutional complementarity. Institutional complementarity is defined as the interdependence where one type of institution rather than another becomes vital in one domain when a fitting institution is present in another domain, and vice versa¹⁶). This concept could compare the additional part to a machine. If the addition is not commensurately-aligned, it cannot work well. For example, does the introduction of accreditation system in disease management promise quality assurance? The abundance of experience and practice in accreditation in healthcare enable the accreditation system in disease management in USA. In the situation of inadequate experience and practice, accreditation alone cannot promise success.

❖ Conclusion

Theoretical and historical analysis in the experience in commercial disease management in USA can give us some suggestions about the quality management mechanism in disease management.

First, accreditation is useful, but it has limitations and requires necessary experience.

Second, US experience tells us that consensus on the evaluation of outcomes in disease management

has not yet been achieved, but that it may be formed through accumulated practices with exchange of knowledge in pragmatic approach. Quality management as knowledge management at a societal level or as a part of the infrastructure is required. It is no small matter to purposefully create the mechanism of circulation and exchange of expertise and knowledge, and to integrate them.

❖ Acknowledgement

I am grateful to the study group, underwritten by the Sompo Japan Foundation, which has conducted the research on the development of disease management in the U.S.A and Japan. I sincerely thank Dr. Gregg Mayer for his help in editing this article. No outside sources of funding were used in the preparation of this article.

❖ References

- 1) Committee on Quality of Health Care in America: Crossing the quality chasm: a new health system for the 21st century. Washington, DC: Institute of Medicine, 2001: 7–9.
- 2) Greenberg L: Accreditation strengthens the disease management bridge over the quality chasm. *Disease Management* 6(1), 3–8 (2003).
- 3) American College of Medical Quality: Core Curriculum for Medical Quality Management. Boston: Jones and Bartlett, 2005.
- 4) Ransom S, Joshi M, and Nash D, eds. *The Healthcare Quality Book*. Chicago: Health Administration, 2005.
- 5) Donabedian A: *An Introduction to Quality Assurance in Health Care*. Oxford University Press: New York, 2003: xxiii.
- 6) Couch J: Disease management: an overview. In: Couch J. ed. *The Health Care Professional's Guide to Disease Management*. Aspen: Gaithersburg, 1998: 1–3.
- 7) http://www.ahipresearch.org/pdfs/2_2002SurvChartBook.pdf (September 8, 2007).
- 8) Disease Management Association of America (DMAA), Outcome Consolidation Steering Committee: *Disease Management Program Evaluation Guide*, First edition. DMAA 2004: 2.
- 9) http://www.pbgh.org/programs/dmep/disease_mgmt_report_11-02.pdf (September 8, 2007).
- 10) <http://www.dismgmt.com> (September 21, 2007).
- 11) <http://www.ncsl.org/programs/health/disesamgtleg04.htm> (December 17, 2006).
- 12) U.S. Department of Health & Human Services, CMS: Report to Congress, Evaluation of Phase I of Medicare Health Support (Formerly Voluntary Chronic Care Improvement) Pilot Program Under Traditional Fee-for-Service Medicare (2007).
- 13) Disease Management Association of America (DMAA), Outcome Consolidation Steering Committee: op.cit.: 7.
- 14) Williamson O: *The Mechanism of Governance*. Oxford University Press: New York, 1996: 178.
- 15) Donabedian A: op.cit.: xxx.
- 16) Aoki M: *Toward a Comparative Institutional Analysis*. The MIT Press: Cambridge, 2001: 225.

❖ Note

- ¹ There is the good example to discuss the country experience. Detmer D: Information technology for quality health care: a summary of United Kingdom and United States experiences. *Quality in Health Care* 9, 181-189 (2000).